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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,444	08/15/2001	Koichi Ito	0425-0847P	9635

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EXAMINER

KIFLE, BRUCK

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 08/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,444

Applicant(s)

Ito et al.

Examiner

Bruck Kifle, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 10, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 22-26, and 32 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 22-26, and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 6) ☐ Other:

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Applicant's amendments and remarks filed 6/10/02 have been received and reviewed.

Claims 1-16, 22-26 and 32 are now pending in this application.

Claim Rejections - 35 USC § 112

Claims 1-16, 22-26 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

iii) The term "substituted" without saying which substituents are intended is indefinite. One skilled in the art cannot say which substituents are permitted and which ones are not. Applicants point to page 32, line 7 to page 35, line 15 of the specification. However, these groups are indicated to "include, but are not limited to" and, therefore, Applicants cannot rely on an open-ended list wherein the metes and bounds are not known. Also, some of the groups are further substituted for which the substituents are not known.

iv) The term "heteroaryl" is indefinite because it is not known how many atoms are present, how many and what kind of heteroatoms are involved, what size ring is intended and how many rings are present. Applicants point to page 31, line 8-21 of the specification. However, the size of the ring and number of heteroatoms permitted are not given here. Applicants need to state whether a 5-6 membered ring with one heteroatom selected from N, O and S is intended or whether more is intended.

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v) The group “optionally substituted amide group” is unclear as to how the group is bonded to the rest of the molecule (carbonyl or nitrogen) and what the rest of this group looks like.

Applicants point to page 35, lines 1-6. There is no description here.

vi) Regarding the term “cycloalkyl”, Applicants need to incorporate the definition in page 31, line 22 because there is no other definition present for cycloalkyl. Thus, the claims need to be amended, as, for example, “C₃-C₈ cycloalkyl”.

vii) It is unclear which diseases are embraced by claims 22 and 23, and which ones are not.

Applicants were unable to say which diseases are intended and which ones are not.

Claims 22-26 are again rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for preventing, treating and ameliorating diseases against which non-N-methyl-D-aspartate excitatory amino acid receptor antagonistic action is effective, against which 2-amino-3-hydroxy-5-methyl-4-isoxazole propionic acid receptor antagonistic action is effective, nerve degeneration diseases, demyelinating nerve diseases and the diseases in claim 26. The basis of this rejection is the same as given in the previous office action and is incorporated herein fully by reference. Applicants argue that the instant compounds have non-NMDA excitatory amino acid receptor antagonistic activity and, thus, preventing, treating and ameliorating of these diseases is enabled. Applicants also point to some references. None of the references says that this is enabled and all are speculative at best. All of the references recognize the difficulty of the task. Applicants are asserting that they have

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succeeded where other have failed. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. Where extensive efforts have all failed, it is reasonable for the Patent and Trademark Office to require proof that the claimed invention actually works for this specific utility. It is well established that a utility rejection is proper when scope of enablement is not reasonably correlated to the scope of the claims. (In re Vaeck 20 USPQ2d 1439, 1444, In re Ferens 163 USPQ 609).

Copious amount of compounds have been excluded from claim 1. If these compounds are excluded to avoid prior art rejections, Applicants should point to these compounds in the prior art to the Examiner because, the disclosure of these compounds is material to the examination of the instant application. Thus, a compound that is excluded by proviso renders obvious a compound of the instant claim when, for example, in the instant claims R¹¹ represents a C3 chloroalkyl group or a C2 iodoalkyl group or any other homologue, analogue or ring position isomer of the excluded compounds should they be present in the prior art. Applicants have not responded to this inquiry

Applicants are again requested to point out the difference in scope of the independent claims. Note that compounds, corresponding compositions, a method of use and a process of making that are of the same scope are considered to form a single inventive concept under PCT Rule 13.1, 37 CFR 1.475(d). The claims are being examined according to the scope of claim 1.

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Copious amount of art is still was still found that anticipates compounds of the instant claims. Examples are given below.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1 is again rejected under 35 U.S.C. 102(b) as being anticipated by Gaozza et al. (J. Heterocycl. Chem. (1970), 7(4), 927-30). The claim still reads on the compound of RN 28669-15-0 (R^1 = substituted aryl; R^2 = aryl). Applicants state that the claims have been amended to overcome this rejection but the claim still reads on this compound.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Soliman et al. (J. Pharm., Sci. (1981), 70(1), 94-6). The claim reads on the compounds of RN 77407-71-7 and 77407-72-8 (see CAS abstract and structures).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Badr et al. (Indian J. Chem., Sect. B (1982), 21B(2), 115-19). The claim reads on the compound of RN 82059-55-0 (see CAS abstract and structures).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Dekeyser et al. (US 4,670,555). The claim reads on the compounds in columns 10-12.

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Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by El-Gendy et al. (Indian J. Chem., Sect. B (1989), 28B(6), 479-85). The claim reads on the compound of RN 125706-95-8 (see CAS abstract and structures).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Matsubara et al. (Chem. Express (1991), 6(6), 411-14. The claim reads on the compound of RN 135585-97-6 (see CAS abstract and structures).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

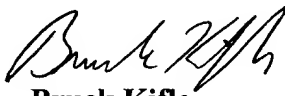
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The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

August 16, 2002


Bruck Kifle
Primary Examiner
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